IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF FLORIDA
AT TAMPA

JAMES E. LOCKARD and VALERIE J. STOBER-LOCKARD	)	
Plaintiffs,	)	
vs.	)	**CASE NO. _____**
NOVARTIS PHARMACEUTICAL CORPORATION, APP PHARMACEUTICALS, INC. AESGEN, INC., BEDFORD LABORATORIES, HOSPIRA, INC., and TEVA PARENTERAL MEDICINES, INC.	)	**JUDGE:** **MAGISTRATE:**
Defendant,	)	**JURY DEMAND**

COMPLAINT AND JURY DEMAND

Plaintiffs, James E. Lockard and Valerie J. Stober-Lockard, by and through counsel, hereby sue the Defendants, Novartis Pharmaceuticals Corporation ("Novartis"), APP Pharmaceuticals, Inc. ("APP"), Aesgen, Inc. ("Aesgen"), Bedford Laboratories ("Bedford"), Hospira, Inc. ("Hospira"), and Teva Parenteral Medicines, Inc. ("Teva") as follows:

I. INTRODUCTION

1. The drugs Aredia® and Zometa®, each produced and marketed by Novartis and other related Novartis entities, each cause and precipitate osteonecrosis of the jaw, mandible or maxilla bone among patients taking those drugs. Generic Aredia (pamidronate) is produced and marketed by APP, Aesgen, Bedford, Hospira and Teva. Osteonecrosis is bone death of an area of the bone. Osteonecrosis of the jaw is a permanently disfiguring and extremely painful condition, and can result in the complete loss of the patient's jaw bone. Mr. Lockard was infused with Aredia® and/or generic

Aredia (pamidronate) and Zometa®, and has suffered osteonecrosis of the jaw bone.

II. PARTIES

A. PLAINTIFF

2. Plaintiffs are citizens and residents of the State of Florida, residing in Palm Harbor, Florida. Mr. Lockard was prescribed, purchased, and was infused with Aredia® and/or generic Aredia (pamidronate) and Zometa®, and as a result thereof suffered severe osteonecrosis of the jaw, including pain, infection, and disfigurement. Mrs. Stober-Lockard has a claim for loss of consortium which arises from the injuries sustained by her husband, Mr. Lockard.

B. DEFENDANT

3. Novartis is a non-resident corporation with its corporate headquarters located at 1 Health Plaza, East Hanover, New Jersey, 07936-1080.

4. At all times relevant hereto, Novartis was engaged in the business of marketing, distributing, promoting, testing, labeling and selling the drugs Aredia® and Zometa®. Novartis, at present or in the past, markets and distributes Aredia® and Zometa® throughout the world, including all fifty states in the United States.

5. APP is a non-resident corporation with its corporate headquarters located at 1501 East Woodfield Road, Suite 300 East, Schaumburg, Illinois 60173-5837.

6. At all times relevant hereto, APP was engaged in the business of marketing, distributing, promoting, testing, labeling and selling generic Aredia (pamidronate). APP at present or in the past, markets and distributes generic Aredia (pamidronate) throughout the world, including all fifty states in the United States.

7. Aesgen is a non-resident corporation with its corporate headquarters located at 2 Research Way, Princeton, New Jersey 08540.

8. At all times relevant hereto, Aesgen was engaged in the business of marketing, distributing, promoting, testing, labeling and selling generic Aredia (pamidronate). Aesgen at present or in the past, markets and distributes generic Aredia (pamidronate) throughout the world, including all fifty states in the United States.

9. Bedford is a non-resident corporation with its corporate headquarters located at 300 Northfield Road, Bedford, Ohio 44146.

10. At all times relevant hereto, Bedford was engaged in the business of marketing, distributing, promoting, testing, labeling and selling generic Aredia (pamidronate). Bedford at present or in the past, markets and distributes generic Aredia (pamidronate) throughout the world, including all fifty states in the United States.

11. Hospira is a non-resident corporation with its corporate headquarters located at 275 N. Field Drive, Lake Forest, Illinois 60045.

12. At all times relevant hereto, Hospira was engaged in the business of marketing, distributing, promoting, testing, labeling and selling generic Aredia (pamidronate). Hospira at present or in the past, markets and distributes generic Aredia (pamidronate) throughout the world, including all fifty states in the United States.

13. Teva is a non-resident corporation with its corporate headquarters located at 19 Hughes, Irvine, California 92618.

14. At all times relevant hereto, Teva was engaged in the business of marketing, distributing, promoting, testing, labeling and selling generic Aredia (pamidronate). Teva at present

or in the past, markets and distributes generic Aredia (pamidronate) throughout the world, including all fifty states in the United States.

III. JURISDICTION AND VENUE

15. This court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332 (diversity jurisdiction) because the amount in controversy exceeds $75,000 exclusive of interest and costs, and because this is an action by Plaintiffs who are citizens of a different state from the Defendants. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(a) and 1391(c).

IV. FACTUAL BACKGROUND

16. Aredia® and/or generic Aredia (pamidronate) and Zometa® are classified as bisphosphonates and are prescribed for the management of metastatic disease to the bone and other bone diseases and conditions. Zometa® is Novartis' "successor" drug to Aredia®, as Aredia® was the first generation version of the drug Zometa®. Zometa® is now marketed by Novartis for all or almost all of the uses for which it previously marketed Aredia®. Aredia® and/or generic Aredia (pamidronate) and Zometa® have been approved by the United States Food and Drug Administration.

17. There are two classes of bisphosphonates: the N-containing (nitrogenous) and non-N-containing (non-nitrogenous) bisphosphonates. The nitrogenous bisphosphonates include the following: pamidronate (Aredia®); zoledronic acid or zoledronate (Zometa®); ibandronate (Bondronat®); risedronate sodium (Actonel®); and alendronate (Fosamax®). The non-nitrogenous bisphosphonates include the following: etridronate (Didronel®); clodronate (Bonefos® and Loron®); and tiludronate (Skelid®). Aredia® and/or generic Aredia (pamidronate) and Zometa® contain a nitrogen atom, whereas etridonate, clodronate, and tiludronate do not.

18. Studies and medical practices report the frequent and common occurrence of osteonecrosis of the jaw in the users of the nitrogenous bisphosphonates, including Aredia® and/or generic Aredia (pamidronate) and Zometa®.

19. The Defendants knew or should have known of the disease phosphorus necrosis of the jaw or "phossy jaw," which appeared in the 1800s in persons mining white phosphorus and persons working in white phosphorus match factories. Phossy jaw had been nearly eliminated in the last century through industrial hygiene. The operation of the active ingredients in both Aredia® and/or generic Aredia (pamidronate) and Zometa® acts and has the same effect as the phosphorus byproducts that caused "phossy jaw." It was foreseeable that any drug with the characteristics of Aredia® and/or generic Aredia (pamidronate) and Zometa® would carry the risk of a "phossy jaw"-like reaction.

20. The process by which old bone is taken away and new bone is created is called "remodeling." Both Aredia® and/or generic Aredia (pamidronate) and Zometa® were designed specifically to affect the "remodeling" process. Medical science knew, and therefore the Defendants knew or should have known, that the jaw operates differently from other bones in the body in that it is subject to unique stresses, and accordingly "remodels" at a far, far greater rate than other bones in the body. Medical science knew, and therefore the Defendants knew or should have known, that bisphosphonate drugs had a "site preference" for high remodeling areas, and therefore would have a heightened effect on bones that remodel at a higher rate. Despite this knowledge not one dentist, maxillofacial surgeon, or other jaw or mouth bone specialist was used or assigned to any clinical trial done by Novartis for either Aredia® or Zometa®. This failure constituted a design flaw in every clinical trial and tainted all information provided to the FDA, other regulatory authorities, and peer

reviewed journals. Nonetheless, despite any intention of examining the jaw or mouth and without utilization of any oral specialists in the clinical trials, Novartis's data captured at least six persons who self-reported ONJ-like symptoms in the Zometa® clinical trials. Novartis failed properly to report this to the FDA as part of Novartis's application for approval to market the drug, and further failed to report other adverse event reports to the FDA in a timely manner.

21. The Defendants knew and or should have known that bisphosphonates, including Aredia® and/or generic Aredia (pamidronate) and Zometa®, inhibit the activity of osteoclasts in the bone. Similarly, the Defendants knew or should have known that bisphosphonates cause changes specific to patients' mandibles (lower jaws) and maxillae (upper jaws) and that these changes appear to be cumulative in nature.

22. The Defendants also knew or should have known that these factors can progress to jaw necrosis (bone death) and osteomyelitis (inflammation of bone marrow).

23. On information and belief, in the year 2002 or before, Novartis was notified by one physician that he had dozens of cases in which patients taking Aredia® had experienced problems so severe that they had lost portions of their jaws. Other oral surgeons during that time frame and before had been reporting such problems to Novartis. On information and belief, Novartis had similar information as to adverse effects caused by its drug Zometa®, which has similar properties and effects as Aredia® and is marketed by Novartis as a more effective replacement for Aredia®. Nevertheless, Novartis did not undertake to advise physicians, notify the consuming public or place information about the possibility of suffering osteonecrosis of the jaw on their products until September of 2004. Novartis did not undertake to notify dental professionals until May of 2005. These efforts to date by Novartis to provide notice are not adequate to provide the public and health

care professionals with the information needed to understand the risks inherent in the use of Aredia® and Zometa®, and indeed are themselves false and misleading.

24. Shortly after Novartis began selling Zometa®, reports of osteonecrosis of the jaw and other dental complications among users further exploded, indicating that Zometa® shared the class effects of the other nitrogenous bisphosphonates including Aredia® and/or generic Aredia (pamidronate). Despite this knowledge, Novartis failed to implement further study of the risk of osteonecrosis of the jaw relative to Zometa® or Aredia®. Rather than evaluating and verifying the safety of Zometa® with respect to osteonecrosis of the jaw, Novartis proposed further uses of Zometa®, notably for osteoporosis under the names Reclast® or Aclasta® or other names, and upon information and belief, urged off-label uses on medical practitioners. Indeed, hundreds of articles have been written by qualified medical professionals and institutions and published in the top medical journals in the world demonstrating that Aredia® and/or generic Aredia (pamidronate) causes osteonecrosis of the jaw at a significant rate, and that Zometa® causes osteonecrosis of the jaw at an even higher rate.

25. Rather than warn patients and the medical community, and despite knowledge by Novartis of increased risk of osteonecrosis of the jaw in patients using Zometa®, Novartis continued and continues to defend and aggressively market Zometa®, while downplaying any unfavorable findings and overstating its benefits. This includes attempting to have it approved for use in the treatment of osteoporosis, and in seeking approval to market the drug for osteoporosis changing the name of the drug to "Reclast®" or "Aclasta®" or other names in order to conceal the link between the drug and osteonecrosis of the jaw.

26. Because of the long "half-life" of the drugs Aredia® and/or general Aredia (pamidronate) and Zometa® in the body, the drug remains in the bones of persons who have been infused with it for at least many, many years or even permanently. For this reason, onset of osteonecrosis of the jaw or worsening of a patient's condition can occur years after infusions of the drug have been discontinued. For this reason, the label indications that call for an infusion of the drug every three-four weeks in perpetuity constitute an overdose.

27. Despite knowledge of the specific risk, the Defendants have failed timely to initiate studies to further investigate risks associated with the use of Aredia® and Zometa®.

28. Further, Novartis had a duty fully to test and evaluate Aredia® and Zometa® prior to their introduction to the market, to ensure that the drugs were safe to use for their intended purpose. Novartis failed to satisfy this duty.

29. Upon information and belief Novartis' Safety Reporting System (also known as "STL") generated errors and affected the reporting of safety data to the FDA and negatively impacted clinical trials. To date the system is obsolete and still generating inaccurate safety data that is being submitted to the FDA.

30. Novartis failed properly to conduct "dosing studies" to ascertain the minimum effective quantities of the drugs Aredia® and Zometa®, and thereby to establish the proper quantities of the drugs to be administered to patients and the proper number of infusions which patients should receive. Identifying the minimum effective dosage and setting the dosage instructions accordingly are critical to avoiding the occurrence of side effects. Novartis, to maximize profit, for most or all label indications specified a dosage and dosing schedule of Zometa® far above any indicated for palliative effect. This dosing schedule, for most indications, calls for an infusion of the drug every

three to four weeks ***forever***, without any end point or time at which the use of the drug should be discontinued. As a result of Novartis's failure to instruct as to the proper dosage, upon information and belief the amount of the drug actually administered to Mr. Lockard constituted an overdose, and contributed to the side effects and harm he suffered.

COUNT I
STRICT LIABILITY

31. Plaintiffs repeat and reallege, as if fully set forth herein, each and every allegation contained in the above paragraphs and further allege:

32. The Defendants were engaged in the business of manufacturing, creating, designing, testing, labeling, sterilizing, packaging, supplying, marketing, selling, advertising and otherwise distributing Aredia® and/or generic Aredia (pamidronate) and Zometa® in interstate commerce, which they sold and distributed throughout the world.

33. Mr. Lockard was using Aredia® and/or generic Aredia (pamidronate) and Zometa® in the manner for which they were intended, or in a reasonably foreseeable manner.

34. Aredia® and/or generic Aredia (pamidronate) and Zometa® were expected to and did reach Mr. Lockard without substantial change in their condition as manufactured, created, designed, tested, labeled, sterilized, packaged, supplied, marketed, sold, advertised and otherwise distributed.

35. Mr. Lockard was not aware of, and reasonably could not have discovered, the actual dangerous nature of Aredia® and/or generic Aredia (pamidronate) and Zometa®.

36. Aredia® and/or generic Aredia (pamidronate) and Zometa® cause increased risk of osteonecrosis of the jaw upon infusion, and therefore constitute a product unreasonably dangerous for normal use due to its defective design, defective manufacture, and the Defendants'

misrepresentations and inadequate facts disclosed to Mr. Lockard and his health care providers including, *inter alia*, the actual risk of developing osteonecrosis of the jaw and the permanent, irreversible harm associated with this disease.

37. As a direct and proximate result of the Defendants' manufacturing, creating, designing, testing, labeling, sterilizing, packaging, supplying, marketing, selling, advertising, and otherwise distributing Aredia® and/or generic Aredia (pamidronate) and Zometa® in interstate commerce, Mr. Lockard has suffered osteonecrosis of the jaw, and is at an increased risk of developing other diseases and conditions.

38. The Defendants, therefore, are strictly liable to Mr. Lockard and he is entitled to compensatory damages. Additionally, the Defendants' conduct was so outrageous as to constitute ill will, bad motive and reckless indifference to the interests of the consumers. Mr. Lockard is therefore entitled to punitive damages in an amount to be proven at trial.

COUNT II
NEGLIGENCE - NEGLIGENT MANUFACTURE

39. Plaintiffs repeat and reallege, as if fully set forth herein, each and every allegation contained in the above paragraphs and further allege:

40. It was the duty of the Defendants to use reasonable care in the manufacturing, creating, designing, testing, sterilizing, packaging, supplying, and otherwise distributing Aredia® and/or generic Aredia (pamidronate) and Zometa®.

41. Contrary to its duty, the Defendants failed to adequately and properly test and inspect Aredia® and/or generic Aredia (pamidronate) and Zometa® so as to ascertain whether or not they were safe and proper for the purpose for which they were designed, manufactured and sold; to

adequately and properly conduct a dosing study or otherwise to test Aredia® and/or generic Aredia (pamidronate) and Zometa® to ascertain the minimum effective dosage and to use this information to instruct users of the drugs and/or their health care providers of the proper dosage so as to minimize the risk of development of osteonecrosis of jaw or other side effects; to utilize and/or implement a reasonably safe design in the manufacture of Aredia® and/or generic Aredia (pamidronate) and Zometa®; and to manufacture Aredia® and/or generic Aredia (pamidronate) and Zometa® in a reasonably safe condition appropriate for the use for which they were intended.

42. The Defendants manufactured and sold Aredia® and/or generic Aredia (pamidronate) and Zometa®, which as constituted is and was a hazard to Plaintiff's health. The Defendants' manufacture and sale of Aredia® and/or generic Aredia (pamidronate) and Zometa® as constituted caused Plaintiff to suffer adverse side effects and disease.

43. The Defendants were otherwise careless and negligent.

44. As a direct and proximate result of the Defendants' negligent, reckless, and careless manufacturing, creating, designing, testing, labeling, sterilizing, packaging, supplying, marketing, selling, advertising, and otherwise distributing Aredia® and/or generic Aredia (pamidronate) and Zometa® in interstate commerce, Mr. Lockard suffered osteonecrosis of the jaw and he has suffered compensatory damages and is entitled to punitive damages in amounts to be proven at trial.

COUNT III
NEGLIGENCE – FAILURE TO WARN

45. Plaintiffs repeat and reallege, as if fully set forth herein, each and every allegation contained in the above paragraphs and further allege:

46. It was the duty of the Defendants to use reasonable care in the labeling, marketing, selling, advertising, and promoting of Aredia® and/or generic Aredia (pamidronate) and Zometa®, and to warn Mr. Lockard and his medical providers of the true risk of osteonecrosis of the jaw and other side effects when using these drugs.

47. Contrary to their duty, the Defendants failed: adequately and properly to warn Plaintiff of the risks of serious complications and bodily harm when Aredia® and/or generic Aredia (pamidronate) and Zometa® are used in the manner for which they were intended; adequately and properly to warn Mr. Lockard of the risks of diseases when Aredia® and/or generic Aredia (pamidronate) and Zometa® are used in a manner for which they were intended; adequately and properly to label Aredia® and/or generic Aredia (pamidronate) and Zometa® so as to warn Mr. Lockard of the risks of complications and disease; and adequately and properly to label Aredia® and/or generic Aredia (pamidronate) and Zometa® so as to warn Mr. Lockard of the risks of osteonecrosis of the jaw.

48. Further, the Defendants failed to meet the standard of care set by the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301, et seq., related amendments and codes and federal regulations provided thereunder, the Sherman Food, Drug and Cosmetic Law, and other applicable laws, statutes and regulations. The Defendants further failed in the following respects:

a. The labeling lacked adequate information on the use of the drugs Aredia® and/or generic Aredia (pamidronate) and Zometa® (21 C.F.R. Section 201.56(a) and (d));

b. The labeling failed to provide adequate warnings of severe and disabling medical conditions including, without limitation, osteonecrosis of the jaw, and other adverse medical conditions as soon as there was reasonable evidence of their association with the drugs (21 C.F.R. 201.57(e));

c. There was inadequate information for patients for the safe and effective use of the Defendants' drugs (21 C.F.R 201.57(f)(2));

d. There was inadequate information regarding special care to be exercised by Plaintiff's doctors for safe and effective use of the Defendants' drugs (21 C.F.R. 201.57(f)(1));

e. The labeling was misleading and promotional (21 C.F.R. 201.56(b)); and

f. The Defendants' acts constitute an adulteration and/or misbranding as defined by the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 331.

49. The Defendants' products Aredia® and/or generic Aredia (pamidronate) and Zometa® were unaccompanied by proper and adequate warnings regarding the risk of osteonecrosis of the jaw associated with the use of the Defendants' products and the scope, severity and duration of such injuries.

50. Despite the Defendants' failure to provide adequate warnings to protect users or consumers of Aredia® and/or generic Aredia (pamidronate) and Zometa®, the Defendants nevertheless continued aggressively to market, promote, distribute, and sell the dangerously defective products.

51. As a result of the Defendants' negligence and the violations of the statutes and regulations listed above, Mr. Lockard suffered injuries and damages as alleged herein.

52. As a direct and proximate result of the Defendants' failure to warn, Mr. Lockard developed osteonecrosis of the jaw, and he has suffered compensatory damages and is entitled to punitive damages in amounts to be proven at trial.

COUNT IV
BREACH OF EXPRESS WARRANTY

53. Plaintiffs repeat and reallege, as if fully set forth herein, each and every allegation contained in the above paragraphs and further allege:

54. The Defendants expressly warranted to Mr. Lockard, by and through statements made by the Defendants or their authorized agents or sales representative, orally and in publications, package inserts and other written materials intended for physicians, medical patients and the general public, that Aredia® and/or generic Aredia (pamidronate) and Zometa® were safe, effective, fit and proper for their intended use.

55. In using Aredia® and/or generic Aredia (pamidronate) and Zometa®, Mr. Lockard and his health care providers relied on the skill, judgment, representations and foregoing express warranties of the Defendants. Said warranties and representations were false in that the aforementioned products were not safe and were unfit for the uses for which they were intended.

56. As a direct and proximate result of the Defendants' breaches of warranties, Mr. Lockard developed osteonecrosis of the jaw, and he has suffered compensatory damages and is entitled to punitive damages in amounts to be proven at trial.

COUNT V
BREACH OF IMPLIED WARRANTY

57. Plaintiffs repeat and reallege, as if fully set forth herein, each and every allegation contained in the above paragraphs and further allege:

58. Prior to the time that Aredia® and/or generic Aredia (pamidronate) and Zometa® were used by Plaintiff, the Defendants impliedly warranted to Mr. Lockard that Aredia® and/or generic Aredia (pamidronate) and Zometa® were of merchantable quality and safe and fit for the use for which they were intended. Mr. Lockard is unskilled in the research, design and manufacture of Aredia® and/or generic Aredia (pamidronate) and Zometa®, and reasonably relied on the skill, judgment and implied warranty of the Defendants in using Aredia® and/or generic Aredia

(pamidronate) and Zometa®.

59. Aredia® and/or generic Aredia (pamidronate) and Zometa® were neither safe for they intended use nor of merchantable quality, as warranted by the Defendants, in that they had dangerous propensities when put to their intended use and would cause severe injuries to the user.

60. As a direct and proximate result of the Defendants' breaches of warranties, Mr. Lockard has developed osteonecrosis of the jaw, and he has suffered compensatory damages and is entitled to punitive damages in amounts to be proven at trial.

COUNT III. LOSS OF CONSORTIUM

61. Plaintiffs incorporate paragraphs 1 through 21 by reference.

62. At all times material hereto, the Plaintiff, Valerie Stober-Lockard was the wife of the Plaintiff, James Lockard, and they were residing in a family relationship in the State of Florida. As a direct and proximate result of the above, Mrs. Stober-Lockard has in the past and will in the future suffer the loss of society, companionship and consortium of her husband, James Lockard.

WHEREFORE, Plaintiffs pray that this honorable Court enter judgment against the Defendants, and in favor of the Plaintiffs, and to award the following relief:

a. Award Mr. Lockard all damages allowed by law to compensate his for the physical injury, pain, suffering, emotional distress, mental anguish, physical disability and physical disfigurement and other losses which he has and will endure;

b. Award Mr. Lockard damages equal to the amount of his past and future medical and health care costs;

c. Award Mrs. Stober-Lockard damages for loss of companionship and consortium with her spouse;

d. Award Mr. Lockard punitive/exemplary d amages to the extent necessary and appropriate to punish and deter the conduct complained of herein;

e. Award Plaintiffs' attorneys' fees and costs, plus interest, as allowed by law; and

f. Award Plaintiffs such other and further legal and equitable relief as this honorable Court deems just and proper.

JURY DEMAND

Plaintiff hereby demands a trial by jury of this action.

LEVIN, PAPANTONIO, THOMAS,
MITCHELL, ECHSNER & PROCTOR, P.A.

By: /s/
Meghan M. Tans, Esq.
Florida Bar No. 0888745
LEVIN, PAPANTONIO, THOMAS, MITCHELL
ECHSNER & PROCTOR, P.A.
316 S. Baylen Street, Suite 600
Pensacola, FL 32502
Telephone: 850-435-7000
Facsimile: 850-435-7020

Robert G. Germany, Esquire
Mississippi Bar No. 4800
PITTMAN, GERMANY, ROBERTS
& WELSH, L.L.P.
410 South President Street (39201)
Post Office Box 22985
Jackson, Mississippi 39225-2985
Telephone: 601- 948-6200
Facsimile: 601- 948-6187

Attorneys for Plaintiffs James E. Lockard and Valerie J. Stober-Lockard

Dated: April 25, 2008